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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	37697-0033	8881
26633	7590	04/10/2008		
HELLER EHRMAN LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			EXAMINER BERMAN, SUSAN W	
			ART UNIT	PAPER NUMBER
			1796	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/764,445

**Applicant(s)**

MERRILL ET AL.

**Examiner**

/Susan W. Berman/

**Art Unit**

1796

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01-10-2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 124-130 and 143-149 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 124-130, 143-149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CC)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Response to Arguments***

Applicant's arguments filed 01-10-2008 have been fully considered but they are not persuasive with respect to the following issues.

With respect to inherent functions or properties in a disclosure the relevant passage referred to in MPEP is "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". The examiner cannot "understand" or assume inherency for a claimed process that has not been described within the instant disclosure. No extrinsic evidence has been made of record in the instant case to support inherency for descriptive matter to support recitations in the instant claims not found in the instant disclosure.

Applicant refers to MPEP 2163 (II) saying that "Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description". With respect to the instant specification and claims, the claims and entire specification have been reviewed and the examiner's positions with respect to support for the claim language within the specification as filed have been carefully explained on the record. The examiner has previously pointed out to applicant how the instant claim language is interpreted in light of and consistent with the specification as filed. It is reiterated that thermal analysis by DSC is not considered to be evidence of a process requiring "remelting" as defined by Shen et al. Applicant is merely melting the treated UHMWPE to ascertain the melting point. See the discussion of DSC in the Declaration under 1.131 of Edward Merrill, section 13, page 6. DSC

was used for thermal analysis, not to treat the samples before analysis. DSC is not taught as a process step for obtaining the desired properties of the UHMWPE products.

With respect to the effective date of invention, applicant clearly states in the Declaration under § 1.131 of Edward Merrill filed 06-20-2007 that methods comprising irradiation followed by “subsequent melting” were disclosed in Application Serial No 08/726,313, filed 10-02-1996 and in Application Serial No. 08/798,638, filed 02-11-1997. See section 10, page 5 of the Declaration.

The data in the Declaration under § 1.131 of Edward Merrill filed 06-20-2007 and discussed in applicant’s remarks has been reconsidered. It is agreed that Experiment 2 in Exhibit 3 shows a sequence of heating and irradiating a sample to achieve a total radiation dose (50 Mrad). The Experiment is titled “Irradiation of barstock while amelt”. The heating between irradiation doses is performed to keep the sample in the melt when irradiated. There is no “subsequent melting” step following the irradiation dose of 50 MRad. Thus the sample is considered to exemplify irradiation in the melt, i.e. the “MIR” process disclosed in the instant specification. The properties of a sample that is irradiated in the melted state followed by cooling and the properties of a sample that is irradiated and then melted followed by cooling and no further irradiation would not be expected to be the same since it is known that irradiation produces free radicals while heating recombines the free radicals present after irradiation, as set forth in the instant claims. Experiment 2 does not include a heating/melting step after (subsequent to) the final irradiation dose of 50 MRad. The data does show that the sample was reheated after each irradiation pass in order to keep the sample in the melt when irradiated. Exhibit 4 also reports “E-Irradiation of the Melt”.

Applicant's arguments with respect to effective filing date being 02-13-1996 for "IR-SM" embodiments are unpersuasive for the reasons set forth above and previously of record.

Shen et al: Applicant argues that US '900 does not qualify as prior art because applicant's initial filing date 02-13-1996 for SN 08/600744 is before Shen et al's earliest filing date of 07-09-1996. This argument is not persuasive because applicant's effective filing date with respect to the rejected claims is the 10-02-1996 filing date of SN 08/726313. As discussed above and in previous office actions in detail, SN 08/600,744 discloses "MIR" and does not disclose "IR-SM" methods. Shen et al clearly disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing in US '900 and in provisional application 60/017852, filed 07-09-1996. The disclosure of Shen et al '900 anticipates applicant's methods and products, as claimed, because the claimed method has an effective filing date of 10-02-1996. Applicant's claims do not recite the "MIR" method disclosed in SN 08/600,744, filed 02/13/1996, as discussed above.

Hyon et al: Applicant argues that Hyon et al (6,168,626, having an effective filing date of May 6, 1996) is antedated by applicant's initial filing. This argument is unpersuasive because Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. It is noted that the Hyon et al filing date of 05/06/1996 is before applicant's 10/02/1996 disclosure of the claimed method comprising irradiating UHMWPE and subsequently melting the irradiated UHMWPE. Applicant further

argues that the product disclosed by Hyon et al is different because of the compression-deformation step. This argument is not persuasive because the comprising language of the instant claims encompasses an unrecited compression-deformation step. There is no comparative data of record to show that the products produced according to the disclosure of Hyon et al and according to the instantly claimed process are significantly and unexpectedly different.

#### ***Claim Interpretation and Effective Filing Date***

Claims 124-130 and 143-149, as amended, recite the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313, filed 10-02-1996. Thus, claims 124-130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of 10/02/1996 with respect to prior art disclosures. The instant claims are considered to be fully supported by the disclosure of SN 08/726,313, but not by SN 08/600744 filed 02-13-1996, wherein a method of irradiating UHMWPE in the molten state is disclosed but subsequent melting after irradiation is not taught. Therefore, the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the 10/02/1996 filing date of SN 08/726,313.

Furthermore, claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN '744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN '744. SN '313 does disclose the swell ratio or degree of oxidation of the disclosed UHMWPE, therefore, the effective filing date for claims 128-129 is considered to be 10/02/1996.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 124-125, 128, 130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claims 124, 125, 130, the recitation “temperature about 150<sup>0</sup>C or above” renders the claims indefinite. If applicant intends to claim a temperature “above 150<sup>0</sup>C”, it should be so stated. If applicant intends to claim a temperature “about 150<sup>0</sup>C”, it should be so stated. With respect to claim 128, the recitation “about 5 or less” render the claim indefinite. If applicant intends to claim “less than 5”, it should be so stated. If applicant intends to claim “about 5”, it should be so stated.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996). Applicant's effective filing

date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (effective filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129.

Claims 125-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and 127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reasons are that Hyon et al disclose the process steps set forth in claim 125 and 128 and the process steps in claim 124 except for sterilizing the implant and that the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps.



### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 126-127 and 135-136

of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they

are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '089 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124,125,129,130,132-134,136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB  
4/8/2008

/Susan W Berman/  
Primary Examiner  
Art Unit 1796

**Application Number****Application/Control No.**

09/764,445

**Applicant(s)/Patent under  
Reexamination**

MERRILL ET AL.

**Examiner**

/Susan W. Berman/

**Art Unit**

1796